K080820

OCT 0 6 2008

510(k) Summary Pursuant to 21 CFR 807.92

1. Submitted By: Avalon Laboratories, LLC
2610 E. Homestead Place
Rancho Dominguez, CA 90220

2. Contact: David C. Furr
FDC Services, LLC
5200 Crystal Water Drive
Austin, Texas 78735
260-402-1598

3. Product: Avalon Elite™ Bi-Caval Dual Lumen Catheter
CFR Section 870.4210
Cardiopulmonary bypass vascular catheter
Class II
Product Code: DWF

4. Common/Trade Name:

Avalon Elite™ Bi-Caval Dual Lumen Catheter

Description:

The Avalon Elite™ Bi-Caval Dual Lumen Catheter is a single catheter with two lumens within the cannula body to collect, separate, and return the blood. The product is offered in a range of sizes to address varying patient size requirements. Inlet ports/openings at the distal tip, and proximally, collect blood from the inferior and superior vena cavae and deliver it to the extracorporeal components consisting of at least, a pump and gas exchange device. Blood returns to the patient through the infusion lumen of the cannula where it exits at a port located in the right atrium. The lumens within the cannula body are completely separate throughout their length. This separation is achieved via a thin septum that divides the otherwise circular internal cross section of the main cannula body. The lumens

become separate, or split out, at the proximal end of the cannula as is typical of many types of dual lumen cannulae/catheters so that they may be attached by conventional tube fittings. The ratio of the drainage lumen to reinfusion lumen cross sectional area is approximately 2 to 1 deriving from typical pre and post pump pressure/flow characteristics. The catheter is supplied with a dilator/introducer to facilitate placement into the vasculature by normal access techniques. The introducer/dilator is intended to follow a pre positioned standard guidewire (not supplied.)

The device is supplied sterile, non-pryogenic and is intended for single use via prescription.

Intended Use:

The Avalon Elite™ Bi-Caval Dual Lumen Catheter is intended for use as a single catheter for both venous drainage and reinfusion of blood via the internal jugular vein during extracorporeal life support procedures.

Technological Characteristics and Substantial Equivalence:

The Avalon Elite™ Bi-Caval Dual Lumen Catheter is substantially equivalent to the Origen Dual Lumen Catheter (K003288). Device comparisons show both products have the same intended use, and similar size ranges, materials, bifurcations, radiopaque tips, and packaging. Both devices are supplied as single use sterile products.

Performance Testing:

The Avalon Elite™ Bi-Caval Dual Lumen Catheter was subjected to numerous tests and comparisons to the predicate device. Testing included Pressure/Burst, Simulated Use, Kink Resistance, Tensile Strength, Flow Characteristics, Hemolysis, and Biocompatibility.

Conclusions:

The studies conducted on Avalon Elite™ Bi-Caval Dual Lumen Catheters demonstrate that the device is substantially equivalent to the predicate device currently in commercial distribution.

The predicate dual lumen catheters and the Avalon dual lumen catheters share similar design, size, and generic materials of construction. Comparisons show that the Avalon products are equivalent to the predicate products in all key areas of features and performance that could affect safety and effectiveness. The intended use is identical to the intended use of the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 6 2008

Avalon Laboratories, LLC
c/o Mr. David Furr
Application Correspondent
5200 Crystal Water Dr.
Austin, TX 78735

Re: K081820
Trade/Device Name: Avalon Elite™ Bi-Caval Dual Lumen Catheter
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: September 15, 2008
Received: September 18, 2008

Dear Mr. Furr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or

any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K081820

Device Name: Avalon Elite™ Bi-Caval Dual Lumen Catheter

Indications for Use:

The Avalon Elite™ Bi-Caval Dual Lumen Catheter is indicated for use as a single catheter for both venous drainage and reinfusion of blood via the internal jugular vein during extracorporeal life support procedures.

Prescription Use X or Over-the-counter use _____
(per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochman
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081820